Fundamental Investigator/Coordinator Orientation

Communication
UMCIRB web site http://www.ecu.edu/irb/
UMCIRB e-mail umcirb@ecu.edu

Required Reading
UMCIRB Standard Operating Practices (SOP) and Policies: http://www.ecu.edu/cs-acad/oric/irb/policies-procedures.cfm

Recommended Reading and Resources
OHRP web site: http://www.hhs.gov/ohrp/
UMCIRB web site www.ecu.edu/irb
Compliance Oversight from OHRP: http://www.hhs.gov/ohrp/compliance/index.html
Declaration of Helsinki: https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/

21 CFR 50 (FDA), Protection of Human Subjects
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfr/cfrsearch.cfm?cfrpart=50&showfr=1

21 CFR 56 (FDA), Institutional Review Boards
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfr/cfrsearch.cfm?cfrpart=56&showfr=1

FDA IRB Information Sheets
http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/GuidancesInformationSheetsandNotices/ucm113709.htm

Differences Between DHHS and FDA
http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/EducationalMaterials/ucm112910.htm

Good Clinical Practice
http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/default.htm

Required Education
UMCIRB website education for the CITI modules: http://www.ecu.edu/cs-acad/oric/irb/education-modules.cfm

Tools
Informed Consent Checklist http://www.hhs.gov/ohrp/policy/consentckls.html
IRB criteria for review (45 CFR 46.111)
http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.111

Updated 01.21.2019
Categories of review—exempt [http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.101](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.101)


**Concepts**
- Vulnerable populations—minors
- Vulnerable populations—prisoners
- Conflict of interest for IRB members
- Informed consent process
- Advertising and recruiting
- Privacy and confidentiality
- Data monitoring
- IRB meeting processes and procedures
- Institutional boilerplate language
- Review of new studies
- Review of requested modifications
- Review of revisions
- Continuing review
- Review of adverse events
- Review of protocol deviations
- Scope of IRB
- Relationship of IRB to the institution
- Relationship of IRB to regulatory agencies
- Research designs
- Office responsibilities
- Committee responsibilities
- Investigator responsibilities